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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/765,269

01/27/2004

Debra Ann Merrill

702-040032

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07/05/2006

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EXAMINER

LILLING, HERBERT J

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/765,269

Applicant(s)

MERRILL ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 17-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/043,660.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Receipt is acknowledged of the preliminary amendment filed April 15, 2004.

2. Claims 17-33 are now pending in this instant application which is a divisional of 10/043,933 now US Patent 6,692,933.

Claims 1-16 have been cancelled.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 17-24, drawn to a method for the preparation of glutamine-rich peptide(s), classified in class 435, subclass 68.1.
- II. Claims 25-29, drawn to glutamine peptides, classified in class 435, subclass one plus.
- III. Claim 30, drawn to a tablet containing a peptide preparation in combination with carriers, diluents and excipients, classified in class 424, subclass 450+.
- IV. Claims 31 and 32, drawn to a liquid beverage or enteral nutrition comprising ingredients for beverages and a peptide preparation, classified in class 426, subclass, one plus.
- V. Claim 33, drawn to a glutamin-rich gluten-free peptide preparation, comprising an enzymatic hydrolysate of gluten protein from which the protein fragments that cause hypersensitivity symptoms in coeliac patients have been removed, classify in Class 435. subclass 68.1.

4. The inventions are distinct, each from the other because:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process, e.g., employing different processing conditions.

Inventions II, III, IV and V are drawn to separate and distinct products which vary in scope since Invention II does not require the specifics of Inventions III - V.

Inventions II and III-V are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a food additive without any additional ingredients and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

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showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one invention is not required for the other invention, thusly the restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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9. Applicant is advised that it appears that Inventions I-IV have been already allowed in parent application 10/043,933 now US Patent 6,692,933 as indicated by the allowed claims as follows:

US-PAT-NO: 6692933

DOCUMENT-IDENTIFIER: US 6692933 B2

TITLE: Method for producing a gluten-free peptide preparation and preparation thus obtained
DATE-ISSUED: February 17, 2004

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
|------|------|-------|----------|---------|
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| Merrill; Debra Ann | Downsville | NY | | |
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| Hunter; Edward Allan | Hancock | NY | | |
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US-CL-CURRENT: 435/68.1

CLAIMS:

What is claimed is:

1. A method for producing a glutamine-rich gluten-free peptide preparation from gluten protein, comprising the steps of: a) enzymatically hydrolysing gluten using one or more proteases to obtain a hydrolysate; b) acidifying the hydrolysate to a pH between 4 and 5; and c) filtering the hydrolysate to obtain the glutamine-rich gluten-free peptide preparation as the filtrate.
2. The method as claimed in claim 1, wherein the proteases are alkaline or neutral proteases.
3. The method as claimed in claim 1, wherein the pH is between 4.2 and 4.8.
4. The method as claimed in claim 1, wherein the pH is between 4.5 and 4.7.
5. The method as claimed in claim 1, wherein proteases are used that are active at a pH above 6.
6. The method as claimed in claim 1, wherein between step b) and c) the enzymes are inactivated.

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7. The method as claimed in claim 6, wherein the enzymes are inactivated by means of heat.
8. The method as claimed in claim 1, wherein the gluten is wheat gluten.
9. A preparation prepared from gluten protein, which is glutamine-rich and gluten-free and is obtained by the method of claim 1.
10. The peptide preparation as claimed in claim 9, wherein the gluten from which the preparation is made is wheat gluten.
11. The peptide preparation as claimed in claim 9 for use as an ingredient in glutamine peptide tablets.
12. The peptide preparation as claimed in claim 9 for use as an ingredient in glutamine peptide liquid beverages.
13. The peptide preparation as claimed in claim 9 for use as an ingredient in glutamine peptide enteral nutrition.
14. Glutamine peptide tablets comprising the carriers, diluents and excipients for tablets and a peptide preparation as claimed in claim 9 as glutamine peptide source.
15. A glutamine peptide liquid beverage comprising ingredients for beverages and a peptide preparation as claimed in claim 1 as glutamine peptide source.
16. A glutamine peptide enteral nutrition comprising carriers, diluents and excipients for enteral nutrition and a peptide preparation as claimed in claim 9 as glutamine peptide source.

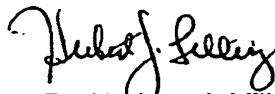
Applicant is entitled to elect any invention to be searched and examined.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is (703) 872-9306** or **SPE Michael Wityshyn whose telephone number is 571-272-0926**. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H.J.Lilling: HJL
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Art Unit 1651
JUNE 19, 2006



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